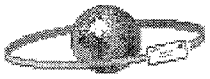
201-14155



gwentwor@cphall.com on 12/20/2002 09:43:34 AM

To: Rtk Chem/DC/USEPA/US@EPA, oppt.ncic@epamail.epa.gov
cc: Richard Hefter/DC/USEPA/US@EPA, Leslie Scott/DC/USEPA/US@EPA

Subject: Submission forThe EPA's High Production Volume Chemical Program

The C.P. Hall Company is pleased to provide the attached dossiers and test plans for N.N-dimethyloctanamide (CAS # 1118-92-9) and N.N-dimethyl-decanamide (CAS # 14433-76-2) as part of its continuing commitment to the U.S. EPA High Production Volume Chemical Program.

These two substances are analogs of very similar chemical structure and properties. We believe that the screening information data needs for this category are fulfilled using the reported data combined with structure activity relationships (SAR) as summarized in the dossiers and presented in the test plan, and that no new testing should be necessary for this program.

Please address any response to this submission to me as the designated technical representative for The C.P. Hall Company.

Gary Wentworth, PhD
Vice President, R&D
The C.P. Hall Company
311 S. Wacker Drive, Suite 4700
Chicago, IL 60606

(See attached file: Octanamide Test Plan.pdf)(See attached file: Decanamide Test Plan.pdf)(See attached file: Test Plan Summary.pdf)

Visit us at: http://www.cphall.com


Octanamide Test Plan.pdf


Decanamide Test Plan.pdf


Test Plan Summary.pdf

201-14155A

TEST PLAN FOR DIMETHYLOCTANAMIDE AND DIMETHYLDECANAMIDE (CHEMICAL ANALOGS)

OVERVIEW

The C.P. Hall Company agrees to sponsor N,N-dimethyloctanamide (CAS No. 1118-92-9) and N,N-dimethyldecanamide (CAS No. 14433-76-2) as two closely related analogs in the Environmental Protection Agency's (EPA) High Production Volume (HPV) Chemical Challenge Program. The company hereby submits a test plan and dossiers for these two substances. It is the intent of the sponsoring company to use existing data combined with structure activity relationships (SAR) to fulfill the Screening Information Set (SIDS) endpoints for environmental fate, ecotoxicity and human health effects.

Table 1. Test Plan Matrix for N,N-dimethyloctanamide (CAS No. 1118-92-9) and N,N-dimethyldecanamide (CAS No. 14433-76-2)

CAS Nos. 1118-92-9 and 14433-76-2	Information	OECD Study	Other	Estimation	GLP	Acceptable	New Testing Required
ENDPOINT	Y/N	Y/N	Y/N	Y/N	Y/N	Y/N	Y/N
PHYS/CHEM PROPERTIES							
Melting Point	Y(C8,C10)	N	Y	N	N	Y	N
Boiling Point	Y(M)	N	Y	N	N	Y	N
	E(B)	N	Y	Y	N	Y	N
Density	Y(C10)	Y	N	N	Y	Y	N
	Y(M)	N	Y	N	N	Y	N
Vapor Pressure	E(C8)	N	Y	Y	N	Y	N
	Y(C10)	Y	N	N	Y	Y	N
Partition Coefficient	Y(B)	Y	N	N	Y	Y	N
Water Solubility	Y(B)	Y	N	N	Y	Y	N
ENVIRONMENTAL FATE							
Photodegradation	Y(C10)	N	Y	N	Y	Y	N
Stability in Water	Y(C10)	N	Y	N	Y	Y	N
Biodegradation	Y(C10)	N	Y	N	Y	Y	N
Transport between Environmental Compartments (Fugacity)	E(B)	N	N	Y	N	Y	N
ECOTOXICITY							
Acute Toxicity to Fish	Y(M)	Y	N	N	Y	Y	N
Acute Toxicity to Aquatic Invertebrates	Y(M)	N	Y	N	Y	Y	N
Toxicity to Aquatic Plants	Y(M)	Y	N	N	Y	Y	N
Toxicity to Terrestrial (NR)	Y(M)	N	Y	N	Y	Y	N
TOXICOLOGICAL DATA							
Acute Toxicity	Y(M)	Y	N	N	Y	Y	N
Repeated Dose Toxicity	Y(M)	Y	N	N	Y	Y	N
Genetic Toxicity-Mutation	Y(M)	Y	N	N	Y	Y	N
Genetic Toxicity-Chromosomal Aberrations	Y(M)	Y	N	N	Y	Y	N
Toxicity to Reproduction	Y(M)[1]	Y	N	N	Y	Y	N
Developmental Toxicity	Y(M)	Y	N	N	Y	Y	N
OTHER TOXICITY DATA							
Skin Irritation (NR)	Y(M)	N	Y	N	Y/N	Y	N
Eye Irritation (NR)	Y(M)	N	Y	N	Y	Y	N
Sensitization (NR)	Y(M)	N	Y	N	Y	Y	N

Y = yes; N = no; E = estimated
(C8) = N,N-dimethyloctanamide only; (C10) = N,N-dimethyldecanamide only; (B) = both C8 and C10; (M) = mixture containing C8 and C10
[1] Reproductive organ toxicity data from 91-day study

TABLE OF CONTENTS

1. Introduction

The C.P. Hall Company submits this test plan for N,N-dimethyloctanamide (CAS No. 1118-92-9) and N,N-dimethyldecanamide (CAS No. 14433-76-2) for hazard review under the Environmental Protection Agency High Production Volume Chemical Program. The technical contact at this company is:

Gary Wentworth
The C.P. Hall Company
5851 West 73rd Street
P. O. Box 910
Bedford Park Illinois 60499-0910
Phone (708) 594-5062

2. Designation of Test Substance

Two chemical analogs are addressed in this test plan as follows:

$CH_3CH_2CH_2CH_2CH_2CH_2CH_2(C=O)N(CH_3)_2$

N,N-Dimethyloctanamide (CAS No. 1118-92-9)

and

$CH_3CH_2CH_2CH_2CH_2CH_2CH_2CH_2CH_2(C=O)N(CH_3)_2$

N,N-Dimethyldecanamide (CAS No. 14433-76-2)

These substances are chemical analogs with the same functionality, differing only in that N,N-dimethyldecanamide has two more carbons in its alkyl chain than N,N-dimethyloctanamide. N,N-dimethyldecanamide is available commercially as Hallcomid M-10®. N,N-dimethyloctanamide is not manufactured in pure form, but is commercially available as the major component in Hallcomid M-8-10®. Hallcomid M-8-10 contains (in weight %) 50-65% N,N-dimethyloctanamide and 37-50% N,N- dimethyldecanamide, with minor impurities N,N-dimethylhexanamide (0-5%) and N,N- dimethyldodecanamide (0-2%). This product will be referred to by its commercial name (Hallcomid M-8-10) for the remainder of this document. Both Hallcomid products are used principally as pesticide inert ingredients.

3. Criteria for Determining Adequacy of Data

All available studies were reviewed and assessed for adequacy according to the standards of Klimisch et al. (1997). Studies receiving a Klimisch rating of 1 or 2 were considered to be adequate.

4. Discussion of Available Test Information

The N,N- dimethyloctanamide and N,N- dimethyldecanamide test plan matrix (as shown in Table 1 on page 2) was constructed after a careful evaluation of all existing data (see below). This matrix is arranged by study type (columns) and screening data endpoints (rows), and indicates if data are provided for each end point in the sets of robust summaries. For the various endpoints data exist for one of the analogs, or for both analogs, or for the commercial product Hallcomid M-8-10. For endpoints where data are missing for one of the analogs, a structure activity relationship (SAR) approach is taken to use data for the other analog or for Hallcomid M-8-10 to predict behavior for the first analog.

4.1 Chemical and Physical Properties

The results of chemical/physical property testing are shown in Table 2.

Table 2. Chemical/physical properties of N,N-dimethyloctanamide and N,N-dimethyldecanamide

Endpoint	Value*	
	N,N-Dimethyloctanamide (CAS No. 1118-92-9)	N,N-Dimethyldecanamide (CAS No. 14433-76-2)
Molecular Weight grams/mol	171.28	199.34
Melting point (° C)	-27 to -22°C[a]	-11 to -7°C[a]
Boiling point (° C)	240 - 265.5 at 1015 hPa**,[b] *257.2 at 1016 hPa*	240 - 265.5 at 1015 hPa**,[b] *289.7 at 1016 hPa*
Relative Density	0.8835**,[b]	0.88 at 20°C[c]
Vapor pressure (hPa at 25° C)	*0 .026*	0.00114 [d] *0 .01*
Partition coefficient (Log Pow or Kow)	2.59 at 23° C[c] *2.46*	3.92 at 24°C[c] *3.44*
Water solubility (mg/l at 25 ° C)	4300 at 20°C[f] *372.3*	344 at 20°C[f] *19.8*

* Values shown in italics were estimated using the EPIWIN model program.
** Value is for Hallcomid M-8-10, a mixture containing 50-60% N,N-dimethyloctanamide and 35-45% N,N-dimethyldecanamide
[a]Internal communication from The C. P. Hall Company; [b] C. P. Hall Company MSDS ; [c]Krohn, 1995; [d]Krohn, 1994a; [e]Krohn, 1993; [f]Krohn, 1994b

4.1.1 Melting Point

Measured melting points were determined by the C. P. Hall Company using differential scanning calorimetry. The test materials were typical commercial Hallcomid M-10 (of =>98% purity) and Hallcomid M-8-10, which is a mixture containing 50-60% N,N-dimethyloctanamide and 35-45% N,N-dimethyldecanamide. Melting points were also estimated using EPIWIN MPBPWIN, but the values were much greater (40.1°C for N,N-Dimethyloctanamide and 60.8°C for N,N-

Dimethyldecanamide) than room temperature. Both products are known to be liquids at room temperature.

4.1.2 Boiling Point

A measured boiling point range of 240-265.5° C is available for Hallcomid M-8-10, a mixture containing 50-60% N,N-dimethyloctanamide and 35-45% N,N-dimethyldecanamide N,N-dimethyloctanamide (The C. P. Hall Company, 2002). Boiling points for the individual chemicals have been estimated by EPIWIN. These boiling points (257.2° C and 289.7° C for N,N-dimethyloctanamide and N,N-dimethyldecanamide, respectively) are in agreement with the measured boiling point for Hallcomid M-8-10, with an expected somewhat higher boiling point for N,N-dimethyldecanamide, which has a longer alkyl chain and higher molecular weight. These data are adequate for addressing this endpoint.

4.1.3 Vapor Pressure

The vapor pressure of 0.00114 hPa measured for N,N-dimethyldecanamide (Krohn, 1994a) is in close agreement with the EPIWIN estimate of 0.01 hPa. The EPIWIN estimate of 0.026 hPa for N,N-dimethyloctanamide is reasonable in comparison with the determinations for N,N-dimethyldecanamide, based on the expected somewhat higher volatility for the shorter chain, and lower molecular weight of N,N-dimethyloctanamide. These data are adequate for characterizing the vapor pressure for these substances

4.1.4 Octanol/Water Partition Coefficient

Log Pows of 2.59 and 3.92 have been determined for N,N-dimethyloctanamide and N,N-dimethyldecanamide (respectively), using ^{14}C-labeled test substance and following OECD Guideline No. 107 (Krohn, 1993). Values of ca. 2.46 and 3.44 (respectively) estimated by EPIWIN KOWWIN, are in the same ranges. These data are adequate for characterizing octanol/water partitioning for these substances.

4.1.5 Water Solubility

Water solubilities of 4.3 g/l and 344 mg/l have been determined for N,N-dimethyloctanamide and N,N-dimethyldecanamide (respectively), using ^{14}C-labeled test substance and following OECD Guideline No. 105 (Krohn, 1994b). EPIWIN WSKOW (v1.40) estimates somewhat lower respective values of 372.3 and 19.8 mg/l based on the estimated Log Kow values given above. It is likely that the measured values are more accurate than the estimated values. The data are adequate for characterizing water solubility of these substances.

4.1.6 Summary/Test Plan for Physical Properties

Both of the test substances are liquids with fairly high boiling points, low vapor pressures, limited water solubility, and positive partition coefficients. Measured data are available for both substances with respect to melting point, water solubility and partition coefficients. The measured density value for N,N-dimethyldecanamide is similar to the value measured for Hallcomid M-8-10, a mixture containing 50-60% N,N-dimethyloctanamide and 35-45% N,N-

dimethyldecanamide. EPIWIN appears to be a good model for estimating the vapor pressure for N,N-dimethyloctanamide, since the EPIWIN-estimated and measured values for dimethyldecanamide are in good agreement. Most measured values for the individual components and Hallcomid M-8-10 are similar to EPIWIN-estimated values, indicating that EPIWIN is a good model to predict physical properties of these materials, with the exception of melting points (see Section 4.1.1).

4.2 Environmental Fate/Pathways

Results of environmental fate modeling and studies are summarized in Table 3.

Table 3. Environmental fate parameters for N,N-dimethyloctanamide and N,N-dimethyldecanamide

Endpoint	**Value***	
	N,N-dimethyloctanamide (CAS No. 1118-92-9)	N,N-dimethyldecanamide (CAS No. 14433-76-2)
Photolysis (Atmospheric $T_{1/2}$, days) Direct Photolysis in air[a] Direct Photolysis in soil[b]	 No data No data	 >30 33
Indirect Photolysis (OH sensitizer) Hydroxyl Radical Rate Constant *cm^3/(molecule * sec)* Atmospheric $T_{1/2}$ (days)	 *2.7×10^{-11}* *0.4*	 *2.98×10^{-11}* *0 .4*
Stability in Water**	*Half-life >1 year*	*Half-life >1 year* Insignificant hydrolysis after 30 days at 25°C at pH 5,7,9[c]
Biodegradation	No data	50 % after 0.5 - 6.5 hrs[d,e] 90% after 0.65 - 7.5 days[d,e]
Henry's Law Constant (atm-m^3/mol)	*2.95×10^{-7}*	*5.2×10^{-7}*
Koc	*118*	*1,130*
Environmental transport (Fugacity Level III mass percentages)	*Air 1.6%* *Water39%;* *Soil 59.5%* *Sediment 0.23%*	*Air 1.19%* *Water 37.8%* *Soil 58.9%* *Sediment 2.09%*

*Values given in italics are estimated by EPIWIN.
**The test substances do not possess functional groups generally recognized to be readily hydrolyzable in water under neutral ambient conditions.
[a]Burri, 1995a; [b]Burri, 1996; [c]Burri, 1995b; [d] Flueckiger,1995; [e] Wyss-Benz and Tschech, 1995

4.2.1 Photodegradation

Direct photolysis of N,N-dimethyldecanamide has been determined in water (Burri, 1995a) and in soil (Burri, 1996), following EPA Guide-line subdivision N 161-2 and EPA Guide-line subdivision N 161-3, respectively. The results of these studies indicate that this substance is not

rapidly photolyzed in either medium. Atmospheric hydroxyl radical-induced photodegradation rate constants of ca. 2.7 x 10^{-11}cm^3/(molecule*sec) and 2.98 x 10^{-11}cm^3/(molecule*sec) have been estimated for N,N-dimethyloctanamide and N,N-dimethyldecanamide using EPIWIN AOP (v1.90). The same program estimates half-lives of 0.4 days for both substances for atmospheric photodegradation with hydroxyl radical as a sensitizer. These results are consistent for both analogs, and indicate that hydroxyl radical-induced atmospheric photodegradation proceeds readily, whereas direct photolysis in water or soil proceeds very slowly. No additional testing is necessary.

4.2.2 Stability in Water

The hydrolysis rate of N,N-dimethyldecanamide has been determined (Burri, 1995b) following EPA Pesticide Assessment Guidelines, Subdivision N. The results of this study indicate insignificant hydrolysis after 30 days at 25°C at pH 5, 7, and 9. EPIWIN modeling of both substances suggests that the amide group is the functionality in the molecule that is most susceptible to hydrolysis, and that hydrolysis at this position is extremely slow (half-life greater than one year). This result is consistent with the measured result and with generally recognized knowledge that amide functions are resistant to hydrolysis under neutral, ambient conditions. Because both test substances contain identical functional groups that are recognized to be resistant to hydrolysis, no testing of this endpoint is recommended.

4.2.3 Fugacity

Level III fugacity modeling has been conducted on the test materials using EPIWIN. The results are nearly identical for both chemical analogs, and indicate that the test substances will partition preferentially to water and soil. The model predicts that the lower homolog, N,N-dimethyloctanamide has a very slightly greater affinity for water. The calculated Henry's Law Constants of 2.95 x 10^{-7} and 5.2 x 10^{-7} atm-m^3/mol suggest that neither analog will rapidly volatilize from water, which in each case is the result of low vapor pressure. Volatilization from soil or sediment is also strictly limited. A soil adsorption/desorption study with N,N-dimethyldecanamide indicates that this material has low or low to medium mobility in soil (Morgenroth, 1995). Water soil partition constants (Koc) of 118 and 1,130 have been estimated using EPIWIN PCKOC for N,N-dimethyloctanamide and N,N-dimethyldecanamide, respectively. These values suggest (as would be expected) that the lower homolog would have somewhat higher soil mobility than N,N-dimethyldecanamide. Additional fugacity testing is not recommended.

4.2.4 Biodegradation

Two well-conducted studies performed with C^{14} labeled N,N-dimethyldecanamide indicate that this material rapidly biodegrades in soil (Flueckiger,1995; Wyss-Benz and Tschech, 1995). The rates of degradation of 50% and 90% of the material in different types of soil ranged from 0.5 to 6.5 hours, and 0.65 to 7.5 days, respectively. Since N,N-dimethyloctanamide is closely related in structure and chemical physical properties to N,N-dimethyldecanamide, this material is also expected to rapidly degrade in soil. Measured data are not available for biodegradation in water. The EPIWIN BIOWIN (v 4.00) program predicts that both substances are readily biodegradable. In addition, aliphatic amides are generally known to readily undergo biodegradation; first to

carboxylic acids, followed by further microcosm-induced breakdown. Results of the well-conducted biodegradation tests in soil, together with estimates from the EPIWIN/BIOWIN program are adequate to characterize this endpoint for N,N-dimethyloctanamide and N,N-dimethyldecanamide.

4.2.5 Summary/Test Plan for Environmental Fate Parameters

Level III fugacity modeling indicates that N,N-dimethyloctanamide and N,N-dimethyldecanamide will tend to partition to water and soil when released to the environment. Although both substances have low vapor pressures and moderately low Henry's Law Constants, EPIWIN modeling predicts that molecules entering the atmosphere will readily undergo hydroxyl radical-induced photodegradation. Well-conducted photodegradation studies are available for N,N-dimethyldecanamide in both soil and water. These studies indicate that the test substance is highly resistant to direct sunlight-induced photolysis in both media. The identical functionality of N,N-dimethyloctanamide suggests that this analog is also resistant to photolysis in these media. The abiotic hydrolysis of N,N-dimethyldecanamide has been studied at pH 3,5, and 7, indicating that this substance is resistant to hydrolysis at ambient temperatures, as is generally recognized for simple aliphatic amides. This study would predict similar behavior for the shorter chain analog, N,N-dimethyloctanamide .

Water-soil partition constants measured for dimethyldecanamide and estimated for N,N-dimethyloctanamide by EPIWIN predict some (albeit limited) soil mobility. Biodegradation studies and modeling indicate that N,N-dimethyldecanamide is readily degraded in soil and water. Modeling results, together with measured determinations of photolysis, hydrolysis and biodegradation are sufficient to characterize environmental fate end points for N,N-dimethyloctanamide and N,N-dimethyldecanamide at the screening level; therefore no further testing for these endpoints is planned.

4.3 Ecotoxicity

4.3.1 Acute Toxicity to Fish

A static, OECD guideline study in rainbow trout was performed with Hallcomid M-8-10 (Dogerloh, 1993). The no observable effect concentration (NOEC) and lethal concentration in 50% of the organisms (LC50) in this 96-hour study were 5 and 21.1 mg/l, respectively. None of the fish exposed to $\leq$ 15.8 mg/l died by 96 hours.

4.3.2 Acute Toxicity to Aquatic Invertebrates

A static EPA guideline study in Daphnia magna was performed with Hallcomid M-8-10 (Forbis, 1990). The NOEC and LC50 values in this 48-hour study were 4 and 7.7 mg/l, respectively.

4.3.3 Acute Toxicity to Aquatic Plants

The toxicity of Hallcomid M-8-10 to Selenastrum capricornutum was tested according to OECD Guideline 201 (Anderson, 1993). For inhibition of growth rate, the NOEC, and effective

concentration in 50% of the organisms (EC50) were 1.80 and 16.06 mg/l for 72 hours, respectively. For inhibition of biomass, the NOEC and the EC50 were < 1.80 and 5.47 mg/l, respectively. Although the pH of the control flasks was slightly higher (0.10 units) at the end of the study than the recommended value, this did not appear to adversely affect the outcome of the test.

4.3.4 Toxicity to other Non-Mammalian Terrestrial Species

Although not required, an EPA guideline test with Hallcomid M-8-10 was performed in bobwhite quail (Grau, 1994). Five groups of 10 birds (five per sex) were given a single oral dose of 0, 200, 400, 800 or 1600 mg/kg Hallcomid M-8-10 by gelatin capsule and observed for 14 days. None of the birds exposed to 800 mg/kg or less Hallcomid M-8-10 died. Transient signs of toxicity (ptosis, loss of equilibrium and/or apathy) were observed in 5 animals treated with 800 mg/kg. Five animals exposed to 1600 mg/kg died and all exhibited convulsions, ptosis, loss of equilibrium and/or apathy on the day of treatment. The no observable effect level (NOEL), lowest observable effect level (LOEL) and lethal dose in 50% of the animals (LD50) values were therefore 400, 800 and 1600 mg/kg, respectively.

4.3.5 Summary/Test Plan for Ecotoxicity

Results of guideline studies in rainbow trout, Daphnia magna and Selenastrum capricornutum show that Hallcomid M-8-10 is of moderate toxicity to these species. An additional study indicates that Hallcomid M-8-10 is of low toxicity to bobwhite quail. The studies that have been performed adequately assess the toxicity of Hallcomid M-8-10 to fish, aquatic invertebrates, algae and birds. Since this material predominantly contains N,N- dimethyl octaneacidamide and N,N- dimethyl decaneacidamide (in approximately equal amounts), and the two materials are closely related in chemical structure and physical properties, the potential for ecotoxicity of the two chemical analogs is not expected to differ substantially from that of Hallcomid M-8-10. Therefore, additional testing with the individual analogs is not necessary.

4.4 Human Health Data

4.4.1 Acute Mammalian Toxicity

This endpoint is filled by sufficient oral, inhalation and dermal toxicity studies in rats performed with Hallcomid M-8-10 (Kreuzmann, 1990a, Pauluhn, 1991, Bomann, 1995). The LD_{50} and LD_{100} (lethal dose in 10%% of animals) values for the oral study were 1,250 mg/kg and 2,500 mg/kg, respectively. The NOEC and LC50 value for inhalation were 118.5 mg/m^3 and greater than 3551 mg/m^3, respectively. The dermal LD_{50} values were 2000 mg/kg for males and between 400 and 2000 mg/kg for females. The NOEL for systemic effects in the dermal study was 200 mg/kg.

Symptoms observed in rats orally treated with 1,250 to 5,000 mg/kg Hallcomid M-8-10 included ataxia, depression, and labored breathing prior to death. Piloerection, red stains around nostrils, brownish urine stains and/or hunched posture were noted up to study day 4 in surviving rats treated with 1.25 or 2.5 g/kg (3/4 and 1/4, respectively). Rats treated orally with 0.025 g/kg

exhibited signs of toxicity only on the day of dosing. Survivors appeared normal after approximately day 5, and had normal necropsies at study termination.

In rats exposed to 586.4 mg/m^3 Hallcomid M-8-10 for 4 hours by inhalation, signs of toxicity such as reddening of the nose, reduced motility and piloerection occurred on the day of exposure only. Most of the rats exposed to higher concentrations also exhibited additional signs and symptoms of respiratory irritation. Symptoms in rats exposed to 2007.6 or 3550.7 mg/m^3 persisted for up to 7 and 14 days, respectively. The necropsy of the one animal that died after exposure to 3550.7 mg/m^3 revealed distended, liver-like and edematous lungs, hydrothorax, and reddened and swollen rhinarium. Surviving rats exposed to 3550.7 mg/m^3 also had a higher incidence of distended lung. Animals exposed to lower concentrations did not exhibit any gross pathological changes with respect to controls.

In the dermal study, four out of 5 females exposed to 400 mg/kg and all rats exposed to higher concentrations exhibited clinical signs of toxicity. These signs generally occurred within 30 minutes of treatment and reversed within 6 days treatment. Skin irritation was noted at the site of administration of most animals exposed to 200 mg/kg, all animals exposed to 400 mg/kg, and all males exposed to 2000 mg/kg. The skin effects lasted from day 2 until the end of the study. One female treated with 50 mg/kg had some squamation at the treatment area. Since none of the others treated with 50 mg/kg had skin reactions, this dose was chosen as the threshold level for local effects.

Since Hallcomid M-8-10 predominantly contains N,N-dimethyloctanamide and N,N-dimethyl decanamide (in approximately equal amounts), and the two materials are closely related in chemical structure and physical properties, the potential for acute mammalian toxicity of the two chemical analogs is not expected to differ substantially from that of Hallcomid M-8-10. Therefore, additional acute toxicity testing with the individual materials is not necessary.

4.4.2 Repeated Dose Mammalian Toxicity

Four repeated dose toxicity studies have been performed with Hallcomid M-8-10. The critical study for the endpoint was a 91-day oral dietary study performed according to OECD guideline 408 (Wirnitzer and Ruhl-Fehlert, 1993). The no observable adverse effect level (NOAEL) for Hallcomid M-8-10 in this study was 2,000 ppm (136.8 mg/kg/day for males and 178.5 mg/kg/day for females), and the lowest observable adverse effect level (LOAEL) was 10,000 ppm (787.6 mg/kg/day for males and 894.6 mg/kg/day for females). Effects noted at 10,000 ppm included emaciation (5/10 males), decreased body weight gain (which normalized during a 28 day recovery period), increased serum cholesterol, increased liver weight, and pathological changes in the kidneys (males only). Similar findings were observed in rats ingesting 10,000 ppm Hallcomid M-8-10 in a 28-day range finding study (Wirnitzer, 1993).

In dogs treated orally by gavage with 20, 100, or 500/1000 mg/kg Hallcomid-M-10 for 6 weeks, no effects were noted at 20 mg/kg/day (Vliegen, 1996). The study personnel set the NOAEL at 100 mg/kg/day; however, the data suggested that there were some treatment-related effects at this dose (i.e. increased vomiting, salivation, and liver, kidney and pancreas weights). Dogs dosed with 500 mg/kg/day for two weeks and 1000 mg/kg/day for the remainder of the study

exhibited vomiting, salivation, increases in some liver enzymes, and increased liver, kidney and pancreas weights.

A five day inhalation study of Hallcomid M-8-10 in rats was conducted according to OECD guidelines (Pauluhn, 1992). In this study, rats were exposed (head and nose only) to an aerosol containing 24.6, 111.2 and 521.2 mg/m^3 material with an average MMAD (and GSD) of 1.4 (1.5) microns. The NOAEL and LOAEL in this study were 111.2 and 521.2 mg/m^3, respectively. Effects noted at 521.2 mg/m^3 included difficulties in breathing, reduced motility, hypothermia and weight loss during treatment, and pathological changes in the nasal and paranasal cavities (females only) after a 15-day recovery period. Lesions in other organs were not observed at necropsy.

Since Hallcomid M-8-10 predominantly contains N,N-dimethyloctanamide and N,N-dimethyl decanamide (in approximately equal amounts), and the two materials are closely related in chemical structure and physical properties, the potential for repeated dose mammalian toxicity of the two analogs is not expected to differ substantially from that of Hallcomid M-8-10. Therefore, additional repeat dose toxicity testing with the individual materials is not necessary.

4.4.3 Genetic Toxicity

4.4.3.1 Mutagenicity

Hallcomid M-8-10 tested negative for mutagenicity in an Ames test (OECD 471) involving *S. typhimurium* strains TA98, TA100, TA1535, and TA1537 in the absence and presence of a metabolic activation system (Herbold, 1992) and a HGPRT assay (OECD 476) conducted with V79 Chinese hamster lung cells in the absence and presence of a metabolic activation system (Brendler-Schwaab, 1994).

The potential for mutagenicity of N,N-dimethyloctanamide and N,N-dimethyldecanamide is not expected to differ substantially from that of Hallcomid M-8-10, since they are the predominant ingredients. Therefore, mutagenicity testing with the individual materials is not necessary.

4.4.3.2 Chromosomal aberration

An OECD Guideline 473 study has been conducted with Hallcomid M-8-10 in Chinese Hamster Ovary Cells in the absence and presence of a metabolic activation system (Gahlmann, 1995). In this study, incubation with up to 160 micrograms/ml (without activation) and 180 micrograms/ml (with activation) did not lead to an increase in the number of aberrants with respect to historical controls. The finding of an increased number of aberrants at 8 hours for cells treated with 180 micrograms/ml in the presence of a metabolic activation system with respect to the solvent control was considered by study personnel to be due to the unusually low number of solvent control cells with aberrations (0.5%).

Based on the fact that N,N-dimethyloctanamide and N,N-dimethyldecanamide are the predominant ingredients of Hallcomid M-8-10 and have similar structures and physical properties, the results of the study with Hallcomid M-8-10 are likely to be predictive of those

with the individual chemical substance analogs. Therefore, additional chromosomal aberration testing with the individual analogs is not necessary.

4.4.3.3 Additional Studies

The ability of Hallcomid M-8-10 to cause unscheduled DNA synthesis in rat primary hepatocytes in the absence of metabolic activation was tested according to OECD Guideline 402 (Brendler-Schwab, 1994). At concentrations up to 98.8 micrograms/ml (the highest concentration that did not cause excessive toxicity), there was no increase in nuclear labeling or the percentage of cells in repair.

4.4.4 Reproductive Toxicity

No mating studies with the individual chemical analogs or Hallcomid M-8-10 have been performed. However, the 91-day rat dietary study that was conducted with Hallcomid M-8-10 included examination of reproductive organs (Wirnitzer and Ruhl-Fehlert, 1993). In this study, the NOAEL for reproductive effects was 10000 ppm, which was higher than the NOAEL for systemic effects. Changes in the testes, prostate and/or epididymis that were noted in 1-2 males from the control, low and high dose groups were not considered to be related to treatment since the incidences and degrees of severity of the lesions in were low (with the exception of one low dose animal that had a high degree of tubular atrophy in the testes) and not dose-dependent.

Results of the developmental toxicity studies (see Section 4.4.5 below) indicate that treatment with up to 450 mg/kg/day Hallcomid M-8-10 in rats or 1000 mg/kg/day of Hallcomid M-8-10 in rabbits during organogenesis has no effect on the number of resorptions, implantations, corpora lutea or viable or nonviable fetuses. At the clearly maternally toxic dose of 450 mg/kg/day, rats had a small increase in post-implantation (embryonic) loss (9.4% vs. 5.6% in controls).

Altogether, the results of the repeated dose and developmental studies suggest that the potential for reproductive toxicity of Hallcomid M-8-10 is low. Therefore, reproductive toxicity testing with N,N-dimethyloctanamide and N,N-dimethyldecanamide is not necessary.

4.4.5 Developmental Toxicity

Results of two OECD guideline studies show that Hallcomid M-8-10 is not a developmental toxicant at non-maternally toxic doses. In a study in rats treated with 50, 150 or 450 mg/kg/day Hallcomid M-8-10 from Days 5 though 15 of gestation (Becker and Biedermann, 1991a), 50 mg/kg/day was the NOAEL for maternal toxicity. Reduced food consumption was observed in dams treated with 150 mg/kg/day (the LOAEL), and more severe signs of toxicity (ventral recumbancy, dyspnea, apathy, coma, and weight loss) were noted in dams treated with 450 mg/kg. Treatment with 50 or 150 mg/kg/day had no effect on any reproductive or fetal parameter. Treatment with 450 mg/kg/day was associated with increased post-implantation (embryonic) loss, reduced fetal weight, and an increased incidence of fetuses (and litters) with skeletal abnormalities (eg. wavy ribs and dumbbell-shaped thoracic bodies) and variations (e.g. non-ossified or incompletely ossified vertebrae, sternebrae or metatarsala). Study personnel did not consider the abnormal skeletal findings in fetuses from dams treated with the high dose to be

indicative of a specific teratogenic effect of the test article because they are commonly found in Wistar rats and correlated with reduced fetal weight.

The results of the OECD study in rabbits (Becker and Biedermann, 1991b) show that Hallcomid M-8-10 is not a developmental toxicant at doses up to 1000 mg/kg/day, which was a maternally toxic dose. Although a number of skeletal variations were observed in this study, there appeared to be no clear-cut, dose-dependent differences in the incidences of variants between treated and control animals. Therefore, study personnel did not consider them to be related to administration of test material.

As the results of the developmental studies with Hallcomid M-8-10 are likely to be predictive of results for N,N-dimethyloctanamide and N,N-dimethyldecanamide, no additional testing is necessary.

4.4.6 Additional Data

4.4.6.1 Skin and Eye Irritation

The results of a DOT corrosivity potential study performed in 6 rabbits indicate that Hallcomid M-8-10 causes moderate-severe skin irritation but is not corrosive (Harris, 1990). An additional skin irritation study performed in one rabbit indicates that the material is corrosive (Kreuzmann, 1990b). Altogether, these results suggest that Hallcomid M-8-10 is severely irritating to the skin. Due to the suspected irritation potential of Hallcomid M-8-10, the material was tested for eye irritation in a single young adult male New Zealand White rabbit (Kreuzmann, 1990c). The total irritation scores ranged from 26 (at 1 hr) to 66 (at Day 4), indicating that the material was highly irritating.

Based on the fact that the two chemical analogs are the predominant ingredients of Hallcomid M-8-10 and have similar structures and physical properties, the results of the study with Hallcomid M-8-10 are likely to be predictive of those with the individual analogs. No additional testing is necessary.

4.4.6.2 Sensitization

The ability of Hallcomid M-8-10 to produce sensitization has been tested in a GLP study in guinea pigs (Kreuzmann, 1990c). After initiation with the highest dose that did not cause irritation (5% test material in 80% ethanol/20% distilled water), challenge with 2.5% test material in acetone did not produce skin irritation. Therefore, Hallcomid M-8-10 did not cause sensitization in the guinea pig. Based on the rational presented above, the results of this study are likely to be predictive of results with N,N-dimethyloctanamide and N,N-dimethyldecanamide. Therefore, testing of these chemical analogs is not necessary.

4.4.7 Summary/Test plan for mammalian toxicity

Adequate studies with Hallcomid M-8-10 have been conducted for all required endpoints. Acute oral, inhalation and dermal toxicity studies show that exposure to fairly large amounts of Hallcomid M-8-10 is required to produce acute toxicity. Inhalation of a very high concentration

(521 mg/m^3) for 5 days causes toxicity to the respiratory system of rats (but not other organs). Results of an OECD guideline, 91-day oral study show that repeated ingestion of doses up to approximately 800 mg/kg/day for 91 days is well tolerated in rats. The material is irritating to the skin and eyes, and is not a sensitizer. Repeated exposure to doses equal to or greater than 100 mg/kg/day also appears to be irritating to the GI tract of dogs, as evidenced by vomiting and increased salivation after dosing. Adequate studies show that Hallcomid M-8-10 is not mutagenic or clastogenic. Results of the 91-day test indicate that the material is not toxic to reproductive organs, and developmental studies in rats and rabbits indicate that the material is not a developmental or reproductive toxicant.

Since Hallcomid M-8-10 predominantly contains N,N-dimethyloctanamide and N,N-dimethyl decanamide (in approximately equal amounts), and the two materials are closely related in chemical structure and physical properties, the potential for mammalian toxicity of the two chemical analogs is not expected to differ substantially from that of Hallcomid M-8-10. Therefore, additional mammalian toxicity testing with the individual materials is not necessary.

5. Summary

In summary, valid data are present to satisfy all physical/chemistry, environmental, aquatic and mammalian toxicity endpoints. In general, measured physical chemistry values for N,N-dimethyloctanamide, N,N-dimethyldecaneacidamide and Hallcomid M-8-10 are similar to each other and to EPIWIN-estimated values for the individual components, indicating that EPIWIN is a good model to predict physical properties and environmental fate of these materials, that data for one analog will be predictive of the other, and those data for Hallcomid M-8-10 can be used to predict behavior of the individual components. No additional testing is necessary.

6. References

Anderson JPE. 1993. Influence of Hallcomid M-8-10 on the growth of the green alga, Selenastrum capricornutum. Bayer AG Study Number E 3230716-2, dated October 18, 1993.

Becker H, Biedermann K. 1991a. Embryotoxicity study (including teratogenicity) with Hallcomid M-8-10 in the rat. RCC Research and Consulting Company Project 274983, dated October 21, 1991.

Becker H, Biedermann K. 1991b. Embryotoxicity study (including teratogenicity) with Hallcomid M-8-10 in the rabbit. RCC Research and Consulting Company AG, Project 275005, dated August 27, 1991.

Bomann W. 1995. Hallcomid M-8-10. Study for acute dermal toxicity in rats. Bayer AG Study Number T 1055380, Report No. 23785, dated 22.02.1995.

Brendler-Schwaab S. 1994. Hallcomid M-8-10. Mutagenicity study for the detection of induced forward mutations in the V79-HGPRT assay in vitro. Study Number T0039125, Bayer AG, Fachbereich Toxicology.

Brendler-Schwab S. 1994. Hallcomid M-8-10. Test on unscheduled DNA synthesis in rat liver primary cell cultures in vitro. Bayer AG, Fachbereich Toxicology, Study Number T7039096.

Burri R. 1995a. Photodegradation study of (1-14C) N,N-dimethyldecanoic acid amide in water at pH 5, R C C Umweltchemie AG P.O. Box CH-4452 Itingen/BL, Switzerland, Study Project Number RCC Project 340312, dated June 15, 1995.

Burri R. 1995b. Hydrolysis determination of (1-14C) N,N-dimethyldecanoic acid amide at pH 5,7, and 9, R C C Umweltchemie AG (P. O. Box CH-4452 Itingen/BL, Switzerland) Study No. RCC Project 340290, dated May 23, 1995.

Burri R. 1996. Photodegradation study of (1-14C) N,N-dimethyldecanoic acid amide on soil, R C C Umweltchemie AG P.O. Box CH-4452 Itingen/BL, Switzerland, Study Project Number RCC Project 370247, dated January 4, 1996.

Dogerloh M. 1993. Hallcomid M-8-10- Acute toxicity to rainbow trout (Oncorhynchus mykiss) in a static test. Bayer AG Study Number E 2800720-9, Report Number DOM 93022, dated August 3, 1993.

EPIWIN AOP (v1.90).

EPIWIN BIOWIN (v 4.00)

EPIWIN HYDROWIN Program (v1.67).

EPIWIN KOWWIN (v1.66).

EPIWIN Level III Fugacity modeling program.

EPIWIN MPBPWIN (v1.40).

EPIWIN WSKOW (v1.40).

Flueckiger J. 1995. [1-14C]N,N-Dimethyldecanoic acid amide: Degradation in three soils incubated under aerobic conditions, RCC Umweltchemie AG, Study Project No. RCC Project 340345, dated October 30, 1995.

Forbis AD. 1990. Acute toxicity of Hallcomid M-8-10 to Daphnia magna. Analytical Bio-Chemistry Laboratories, Inc., Study Report Number 38938, dated October 24, 1990.

Gahlmann R. 1995. Hallcomid M-8-10. In vitro mammalian chromosome aberration test with Chinese Hamster Ovary (CHO) cells. Study Number T7039113, Bayer AG, Fachberiech Toxicology.

Grau R. 1994. Hallcomid M-8-10 (technical grade). Acute oral toxicity to Bobwhite Quail. Bayer AG Laboratory Project E2920732-5, Report No. VB-024, dated July 25, 1994.

Harris SR. 1990. DOT Corrosivity potential study in rabbits of Hallcomid M-8-10. Hill Top Biolabs Project No. 90-4206-21 (A) for The C. P. Hall Company. Report dated Dec. 10, 1990

Herbold BA. 1992. Hallcomid M-8-10 Salmonella/Microsome Test. Study Number T3039100, Bayer AG, Fachbereich Toxicology.

Klimisch HJ, Andreae M and Tillmann U. 1997. A systematic approach for evaluating the quality of experimental toxicological and ecotoxicological data. Reg Tox Pharm 25:1-5.

Kreuzmann JJ. 1990a. Acute oral toxicity in rats-median lethal dosage determination. Hill Top Biolabs Project No. 90-4047-21(A) for C. P. Hall. Revised Report I, dated Aug 23, 1990.)

Kreuzmann JJ. 1990b. Primary skin irritation study in rabbits of Hallcomid M-8-10. Hill Top Biolabs Project No. 90-4047-21 for C. P. Hall. Report dated May 8, 1990.

Kreuzmann JJ. 1990c. Primary eye irritation study in rabbits of Hallcomid M-8-10. Hill Top Biolabs Project No. 90-4047-21 (D) for The C. P. Hall Company. Report dated May 8, 1990.

Kreuzmann JJ. 1990d. Delayed contact hypersensitivity study in guinea pigs of Hallcomid M-8-10. Hill Top Biolabs Project No. 90-4047-21 (E) for The C. P. Hall Company. Report dated May 8, 1990.

Krohn J. 1993. Partition coefficient of dimethyloctanamide and dimethyldecanamide, Beyer AG, Leverkusen Germany, Laboratory Project ID 14 700 0780, dated December 3, 1993.

Krohn J. 1994a. Vapour pressure curve of dimethyldecanamide, Bayer AG, Leverkusen, Germany, Laboratory Project ID 12 200 0782, dated June 30, 1994.

Krohn J. 1994b. Water solubility of dimethyloctanamide and dimethyldecanamide, Bayer AG, Leverkusen, Germany, Laboratory Project ID 14 410 0779, dated June 9, 1994.

Krohn J. 1995. Density of dimethyldecanamide, Bayer AG, Leverkusen Germany, Laboratory Project ID 14 180 0855, dated January 6, 1995.

Morgenroth U. 1995. Adsorption/desorption of N,N-dimethyldecanoic acid amide on four soils, RCC Umweltchemie AG, Study Project No. RCC Project 340356, dated December 20, 1995.

Pauluhn J. 1991. Hallcomid M-8-10. Acute inhalation toxicity in the rat. Bayer AG Study No. T9039809, Report No. 20386, dated July 1, 1991.

Pauluhn J. 1992. Orientation study for subacute inhalation toxicity in the rat (Expos: 5 x 6 h). Bayer AG Study No T7039960, Report No. 21679, dated Sept 17, 1992.

The C. P. Hall Company. 2002. Material Safety Data Sheet (MSDS) for Hallcomid M-8-10

Vliegen M. 1996. Hallcomid M-8-10. Subacute toxicity in dogs (6-week study by oral

administration, gavage). Bayer AG Study No T8055297, Report No. 25057, dated May 9, 1996.

Wirnitzer U and Ruhl-Fehlert C. 1993. Hallcomid M-8-10. Study on subacute toxicity study in Wistar rats (Administration in feed over 13 weeks with 4-week post-treatment observation). Bayer AG Study No. T4041117, Report No. 22931, dated March 11, 1993.

Wirnitzer U. 1993. Hallcomid M-8-10: Study for subacute toxicity on Wistar rats (Feeding study for range-finding over 4 weeks). Bayer AG Study No. T9041022, Report No. 22117, dated March 11, 1993.

Wyss-Benz M and Tschech A. 1995. [1-14C]N,N-Dimethyldecanoic acid amide: Degradation and metabolism in one U.S. soil, incubated under aerobic conditions, RCC Umweltchemie AG, Study Project No. RCC Project 340334, dated September 7, 1995.

201-14155B

Robust Summaries and Dossier for N,N-Dimethyldecanamide (CAS No. 14433-76-2)

Existing Chemical	:	ID: 14433-76-2
CAS No.	:	14433-76-2
EINECS Name	:	N,N-dimethyldecan-1-amide
EINECS No.	:	238-405-1
Molecular Formula	:	C12H25NO

Producer Related Part

Company	:	PCA Services, Inc.
Creation date	:	20.09.0002

Substance Related Part

Company	:	PCA Services, Inc.
Creation date	:	20.09.0002
Memo	:	
Printing date	:	12.11.2002
Revision date	:	
Date of last Update	:	11.11.2002
Number of Pages	:	22
Chapter (profile)	:	Chapter: 1, 2, 3, 4, 5, 7
Reliability (profile)	:	Reliability: without reliability, 1, 2, 3, 4
Flags (profile)	:	Flags: without flag, confidential, non confidential, WGK (DE), TA-Luft (DE), Material Safety Dataset, Risk Assessment, Directive 67/548/EEC, SIDS

1.0.1 OECD AND COMPANY INFORMATION

Type	:	cooperating company
Name	:	The C. P. Hall Company
Partner	:	
Date	:	20.09.2002
Street	:	5851 West 73rd Street
Town	:	60499 Bedford Park, Illinois
Country	:	United States
Phone	:	
Telefax	:	
Telex	:	
Cedex	:	
Reliability	:	(1) valid without restriction

24.09.2002

1.0.2 LOCATION OF PRODUCTION SITE

1.0.3 IDENTITY OF RECIPIENTS

1.1 GENERAL SUBSTANCE INFORMATION

Substance type	:	organic
Physical status	:	liquid
Purity	:	% w/w

19.09.2002

1.1.0 DETAILS ON TEMPLATE

1.1.1 SPECTRA

1.2 SYNONYMS

decanoic acid dimethylamide
21.09.2002

N,N-dimethylcapramide
21.09.2002

N,N-dimethyldecanamide
21.09.2002

N,N-dimethyldecanoic acid amide

Reliability	:	(1) valid without restriction

21.09.2002

1.3 IMPURITIES

1.4 ADDITIVES

1.5 QUANTITY

1.6.1 LABELLING

1.6.2 CLASSIFICATION

1.7 USE PATTERN

1.7.1 TECHNOLOGY PRODUCTION/USE

1.8 OCCUPATIONAL EXPOSURE LIMIT VALUES

1.9 SOURCE OF EXPOSURE

1.10.1 RECOMMENDATIONS/PRECAUTIONARY MEASURES

1.10.2 EMERGENCY MEASURES

1.11 PACKAGING

1.12 POSSIB. OF RENDERING SUBST. HARMLESS

1.13 STATEMENTS CONCERNING WASTE

1.14.1 WATER POLLUTION

1.14.2 MAJOR ACCIDENT HAZARDS

1.14.3 AIR POLLUTION

1.15 ADDITIONAL REMARKS

1.16 LAST LITERATURE SEARCH

1.17 REVIEWS

1.18 LISTINGS E.G. CHEMICAL INVENTORIES

2.1 MELTING POINT

Method	:	Other: Differential scanning Calorimetry (DSC)
Year	:	2002
GLP	:	No
Test substance	:	as prescribed by 1.1 - 1.4 (Typical commercial grade material, purity =>98%).
Result	:	-11 to –7 ° C
Test Condition	:	The heating/cooling rate was 10C/min. The lower temperature given is the onset of the melting curve and the higher temperature is the peak.
Reliability	:	(2) Valid with restrictions. Study details not documented.
Reference	:	Internal company data from The CP Hall Company

Sublimation	:	
Method	:	other
Year	:	2002
GLP	:	no
Test substance	:	as prescribed by 1.1 - 1.4
Result	:	EPIWIN MBPBWIN estimated a melting point of 60.83 degrees C. This estimation is unreliable, since the chemical is known to be a liquid at room temperature.
Reliability	:	(3) invalid

20.09.2002 (10)

2.2 BOILING POINT

Value	:	ca. 289.7 ° C at 1016 hPa
Decomposition	:	
Method	:	other
Year	:	2002
GLP	:	no
Test substance	:	as prescribed by 1.1 - 1.4
Method	:	EPIWIN MPBPWIN (v1.40) uses the adapted Stein and Brown method to estimate boiling point. The input into the EPIWIN program was the CAS No. of the test substance.
Reliability	:	(2) valid with restrictions

20.09.2002 (11)

2.3 DENSITY

Type	:	relative density
Value	:	= .88 at ° C
Method	:	OECD Guide-line 109 "Density of Liquids and Solids"
Year	:	1995
GLP	:	yes
Test substance	:	as prescribed by 1.1 - 1.4
Method	:	The test method was OECD Guideline No. 109, corresponding to EC Guideline A.3.
Test substance	:	The test substance was dimethyldecanamide, Batch 9301ELB02. The chemical identity was confirmed by H-NMR-spectrum and mass spectrum. The test material purity was determined to be 98.8% by GLC.
Reliability	:	(1) valid without restriction

20.09.2002 (1)

2.3.1 GRANULOMETRY

2.4 VAPOUR PRESSURE

Value	:	= .00114 hPa at 25° C
Decomposition	:	
Method		OECD Guide-line 104 "Vapour Pressure Curve"
Year	:	1994
GLP	:	yes
Test substance	:	as prescribed by 1.1 - 1.4
Method	:	OECD Guideline No. 104, corresponding to EEC Guideline A4.
Result	:	The vapor pressure at 20 degrees C was calculated t0 be 0.000668 hPa.
Test condition	:	The gas saturation method used for the vapor pressure determination passes nitrogen as an inert carrier gas over the test substance, thereby saturating the nitrogen with vapor up to the vapor pressure of the test substance and transporting the vapor with the nitrogen flow into a trap. After quantitative determination of the substance in the trap, the vapor pressure, i.e., the partial vapor pressure can be calculated, using the general gas equation and from the volume of nitrogen used to transport this quantity of substance. The apparatus used for the measurement consisted of a gas supply unit, a saturator column, and a trap. Decanophenone was used as the internal standard for HPLC determinations. The determination consisted of the following steps: loading the saturator columns with the test substance, saturation of the carrier gas stream with the test substance, preparation of the samples collected for analytical determination of the test substance, quantitative HPLC determination of the test substance, and calculation of the vapor pressures and generation of the vapor pressure curve. The analytical concentration measurements were validated, and the relative response of dimethyldecanamide and decanophenone at various concentrations were determined. The stability of the solutions and the stability of the test substance under the experimental conditions were confirmed. No decomposition or evaporation from the test containers and equipment were observed over 16 days.
Test substance	:	The test substance was Hallcomid C10 (trade name), batch 930129ELB02. Mass spectra and H-NMR-spectra were used to confirm the chemical identity of the test substance. The test substance was certified by GLC to be 98.8% pure.
Reliability	:	(1) valid without restriction
08.10.2002		(16)

Value	:	ca. .002 hPa at 25° C
Decomposition	:	
Method		other (calculated)
Year	:	2002
GLP	:	no
Test substance	:	as prescribed by 1.1 - 1.4
Method	:	EPIWIN MPBPWIN (v1.40) used the Modified Grain Method for estimating vapor pressure. Input to the EPIWIN program was the CAS No. for the test substance.
Reliability	:	(2) valid with restrictions
21.09.2002		(9)

2.5 PARTITION COEFFICIENT

Log pow	:	= 3.92 at 24° C

Method		OECD Guide-line 107 "Partition Coefficient (n-octanol/water), Flask-shaking Method"
Year	:	1993
GLP	:	yes
Test substance	:	as prescribed by 1.1 - 1.4
Method	:	Shaking method according to OECD Guidelines No. 107(corresponding to EEC Guidelines A8).
Test condition	:	A preliminary test was performed according to the shaking method with the partition coefficient determined to be 6700 (log Pow 3.83). For the studies, demineralized water was used, the purity of which was equivalent to that of bidistilled water from a quartz distillation apparatus. The water and the n-octanol (purity >99%) were mutually saturated by stirring with a sufficient quantity of the other component of the partition system. The test vessels containing stock solution, water and n-octanol were rotated 100 times, through 180 degrees to thoroughly mix the contents. The solutions from both phases were analyzed using a modular HPLC chromatograph, Model LC-6A with spectrophotometric SPD-6A. It became evident from the chromatograms that no degradation of the test substance occurred under test conditions. Calibration solutions of the test substances at different concentration levels were measured in connection with the determinations of the partition coefficients in order to establish reproducibility and linearity of the ahalytical HPLC method.
Test substance	:	The test substance was Hallcomid C10 (tradename), Batch 930129ELB02, chemical identity confirmed by mass spectra and H-NMR-spectra, and purity determined by GLC to be 98.8% pure.
Reliability	:	(1) valid without restriction
08.10.2002		(15)
Log pow	:	ca. 3.44 at ° C
Method		other (calculated)
Year	:	2002
GLP	:	no
Test substance	:	as prescribed by 1.1 - 1.4
Method	:	EPIWIN KOWWIN calculates Log Kow by summing individual contributions to Log Kow for each fragment in the molecule, based on values assigned in the program for each fragment.
Reliability	:	(2) valid with restrictions
20.09.2002		(8)

2.6.1 WATER SOLUBILITY

Value	:	= 340 mg/l at 20 ° C
Qualitative	:	
Pka	:	at 25 ° C
PH	:	= 7 at and ° C
Method	:	OECD Guide-line 105 "Water Solubility"
Year	:	1994
GLP	:	yes
Test substance	:	as prescribed by 1.1 - 1.4
Method	:	Flask method according to OECD-Guidelines No. 105 (corresponding to EC Guidelines A6).
Remark	:	Although the solubility was established only for neutral water in equilibrium with atmospheric carbon dioxide, solubilities will be similar in the cases of slightly acidic or alkaline solutions (pH 3-9), because salt formation by

deprotonation or protonation in this pH range can be ruled out due to the chemical structure of an aliphatic tertiary carboxylic acid amide of the coupound.

Test condition : For the study, demineralized water was used, the purity of which was equivalent to that of bidistilled water from a quartz distillation apparatus. The water used was not buffered and in equilibrium with atmospheric carbon dioxide The water and the n-octanol (purity >99%) were mutually saturated by stirring with a sufficient quantity of the other component of the partition system.

1.0 grams of test substance were weighed into a 100 ml Erlenmeyer flask and added with 100 ml water. After a magnetic bar had been introduced, the flasks were put into a water bath thermostated at 20 degrees C. The test substance was suspended by intensively stirring by means of a magnetic stirrer below the water-bath. In order to estimate the rate of establishment of the solubility equilibrium, approx. 10 ml of suspension were sampled after increased stirring times, filled into a polyethylene beaker and centrifuged in a thermostatically controlled centrifuge at 18000 rpm and 20 degrees C for 50 mins. The upper layer of the centrifuged sample was removed and discarded using a Teflon tube and applying reduced pressure. Portions from the clear solutions of the middle layer were diluted 1:10 and transferred into sampler bottles for concentration by HPLC

The solutions from both phases were analyzed using a modular HPLC chromatograph, Model LC-6A with spectrophotometric SPD-6A. The concentration of samples resulting from the saturation procedure was measured in a sequence after the 24 hours sample had been drawn and again after further 24 hours of standing at ambient temperature. By comparing relative responses with that of freshly prepared calibration solutions, it became evident that no degradation of the test substance occurred under test conditions.

It became evident from the concentration measurements that the solubility equilibrium was reached after 30 minutes of stirring.

Test substance : The test substance was Hallcomid C10 (tradename), Batch 930129ELB02, chemical identity confirmed by mass spectra and H-NMR-spectra, and purity determined by GLC to be 98.8%.

Reliability : (1) valid without restriction
08.10.2002 (17)

Value : ca. 50.51 mg/l at ° C
Qualitative :
Pka : at 25 ° C
PH : at and ° C
Method : other
Year : 2002
GLP : no
Test substance : as prescribed by 1.1 - 1.4
Method : EPIWIN WSKOW calculates water solubility based on Log Kow, using the equation Log S (mol/L) = 0.796 - 0.854 Log Kow - 0.00728 MW + correction. The Log Kow inputted was 3.44.

Reliability : (2) valid with restrictions
20.09.2002 (12)

2.6.2 SURFACE TENSION

2.7 FLASH POINT

2.8 AUTO FLAMMABILITY

2.9 FLAMMABILITY

2.10 EXPLOSIVE PROPERTIES

2.11 OXIDIZING PROPERTIES

2.12 ADDITIONAL REMARKS

3.1.1 PHOTODEGRADATION

Type	:	water
Light source	:	Xenon lamp
Light spect.	:	= 300 - 800 nm
Rel. intensity	:	= .9 - 1 based on Intensity of Sunlight
Spectr. of subst.	:	lambda (max, >295nm) : 290 nm epsilon (max) : epsilon (295) :
Conc. of subst.	:	at 25 degree C
Direct photolysis		
Halflife t1/2	:	> 30 day
Degradation	:	% after
Quantum yield	:	
Deg. Product	:	
Method	:	EPA Guide-line subdivision N 161-2 "Photodegradation studies in water"
Year	:	1995
GLP	:	yes
Test substance	:	as prescribed by 1.1 - 1.4
Method	:	R C C Umweltchemic AG states that it is responsible for the performance of the study according to EPA guideline: (U.S.) EPA 540/9-82-021: Pesticide Assessment Guidelines, Subdivision N: Chemistry Environmental Fate, Section 161-2: Photodegradation Studies in Water. Also followed was (U.S.)EPA: Pesticide Assessment Guidelines, Subdivision N, Environmental Fate, Section 161-2, Aqueous Photolysis Studies, Standard Evaluation Procedure for Aqueous Photolysis Studies, 1985.
Result	:	The amounts of radioactivity were almost completely recovered after 30 days of illuminiation (92.4-98.8%). The amounts recovered after incubation in the dark for 30 days (the control) was 93.1-101.7%. Based on TLC- and HPLC-analyses, almost exclusively the parent compound (CAS No. 14433-76-2) was found at all time intervals for the illuminated samples and for the dark controls. Cumulative volatiles increased during the period of illumination from <0.05% to 0.3% at day 30.
Test condition	:	The test material was stored in the dark at about - 20 degrees C. Reference compounds that were possible products of photodegradation were collected and characterized by TLC for comparison with degradation products. Bidistilled water was used, with a pH of 6.0, conductivity 2.3 uS/cm, and hardness <0.2 mmol/l. The pH was adjusted to 5.0 using sodium acetate and acetic acid buffering, since it had been demonstrated that the test article was hydrolytically most stable at that pH. Before incubation, test solutions were sterilized by a sterile filter, and the application devices and vessels were autoclaved for at least 30 min. at 120 degrees C to exclude the possibility of microbial degradation. The study was performed in the ORIGINAL HANAU SUNTEST apparatus. The Xenon burner used had a max. 765 W/m2 at max. UV filtering (lambda <800 nm) with controllable irradiance between 400-765 W/m2. The radiation in the range between 300-800nm is very similar to the global radiation of sunlight according to daylight D 65. Light intensity was measured using a spectroradiometer LI-COR Model LI-1800. The average light intensity during incubation was 97.0 KLux, which is comparable to the light intensity of natural daylight in the summer. An aliquot of 200 ml sterile buffer solution containing the test article was illuminated with a light/dark cycle of 12 hours at a temperature maintained at 25 +-1 degrees C. The system was continuously stirred with a magnetic stirrer ventilated through a sterile filter with air. The outcoming air was

passed through a CO2 trapping system (NaOH) and through ethylene glycol for absorption of volatiles. For control, a sterile reaction vessel with an aliquot of 150 ml buffered test solution was incubated under identical conditions in the dark.

During the 30 day illumination period samples were taken at 0, 3, 7, 14, 21 and 30 days. After determination of total radioreactivity, the samples were further characterized for parent compound and degradation products. pH of the test solutions were monitored at days 0, 14, and 30 of the illumination period. The aqueous samples were analysed by TLC and HPLC.

Test substance : N, N-Dimethyldecanoic acid amide (CAS No. 14433-76-2) Batch Number 930129ELB02, 98.8% purity on Dec. 21, 1992 as confirmed by High performance liquid chromatography. The 14 C labelled material was labelled on the carbonyl carbon and had an average purity of 97.6% Multiple purity checks indicated that the test substance is stable under the storage conditions.

Conclusion : The study author concluded that the study showed that N,N-dimethyldecanoic acid amide was stable against direct photolysis at pH 5.0 during illumination at 25 degrees C for 30 days, and that the half life was much greater than 30 days..

Reliability : (1) valid without restriction
08.10.2002 (3)

Type : soil
Light source : Xenon lamp
Light spect. : = 300 - 800 nm
Rel. intensity : = .9 - 1 based on Intensity of Sunlight
Spectr. of subst. : lambda (max, >295nm) : 290 nm
epsilon (max) :
epsilon (295) :
Conc. of subst. : 4 mg/l at 25 degree C
Direct photolysis
Halflife t1/2 : = 33 day
Degradation : % after
Quantum yield :
Deg. Product : yes
Method : EPA Guide-line subdivision N 161-3 "Photodegradation studies on soil"
Year : 1996
GLP : yes
Test substance : as prescribed by 1.1 - 1.4
Result : Total recoveries of radioactivity amounted to 91.8-101.3% and 96.5-101.3% of radioactivity applied in illuminated and dark samples respectively. In the illuminated soil samples, cumulative volatiles, characterized as 14CO2, increased to 16.0% at day 30, indicating that complete mineralization occurred. Negligible amounts of volatiles besides CO2 were found in the ethylene glycol trap (0.1%). In the control samples incubated in the dark, negligible amounts of volatiles wee found in the ethylene glycol trap.

In the illuminated samples, the parent compound decreased from 94.7-96.6% at day 0 to 47.3-53.7% at day 30. In the control sample incubated in the dark, the parent compound decreased slightly to 86.8% at day 30.

N,N-dimethylsuccinic acid monoamide was identified as the primary degradation product other than CO2

Test condition : The test article was analytically confirmed to be stable on storage and in the test solutions.

The study was performed in the ORIGINAL HANAU SUNTEST CPS apparatus, equipped with a xenon lamp. The xenon lamp provided a radiation in the range between 300-800 nm. Wavelengths <290 nm were

filtered out.

The soil was sampled in Porterville Calif. and classified as sandy loam. The soil was prepared as thin layers on glass plates. To evaluate degradation by soil microorganisms during photolysis, vital soil (unsterilized) was used. In this way, taking into account the controls in the dark, degradation by specific soil processes could be separated from the photolysis process. The test substance was applied to the soil at an average dose level of 4.1 mg/kg and exposed to artificial light using a 12 hour light/dark cycle during 30 days.

During illumination samples were taken at the intervals of 0, 1, 3, 7, 14, and 30 days. Volatiles were measured for both the illuminated sample and an identical sample used as a control kept incubated under identical conditions, except being kept in the dark. Volatiles and 14CO2 were measured.

Light intensity was measured using a spectroradiometer (LI-1800). Light intensity was set to about 90 KLux and averaged 92.1 KLux. Radioactivity was determined on Packard liquid scintillation counters equipped with DPM.

Test substance : N, N-Dimethyldecanoic acid amide (CAS No. 14433-76-2) Batch Number 930129ELB02, 98.8% purity on Dec. 21, 1992 as confirmed by High performance liquid chromatography. The 14 C labelled material was labelled on the carbonyl carbon and had a purity of 98.6% just prior to treatment.

Conclusion : The author of study concluded that the data indicated that degradation of the test material on soil under illumination conditions simulating natural sunlight proceeded with a calculated half-life of 33.0 days.

Reliability : (1) valid without restriction
08.10.2002 (4)

Type : air
Light source :
Light spect. : nm
Rel. intensity : based on Intensity of Sunlight
Indirect photolysis
Sensitizer : OH
Conc. of sens. :
Rate constant : ca. .0000000000298 cm3/(molecule*sec)
Degradation : ca. 50 % after .4 day
Deg. Product :
Method : other (calculated)
Year : 2002
GLP : no
Test substance : as prescribed by 1.1 - 1.4
Method : EPIWIN AOP calculates the overall OH radical rate constant by summing up individual rate constants assigned in the program to reactions of OH radicals with individual bonds in the molecule. The half life is then calculated assuming first order kinetics with a constant concentration of OH radical.

Reliability : (2) valid with restrictions
24.09.2002 (5)

3.1.2 STABILITY IN WATER

Type : abiotic
t1/2 pH4 : at degree C
t1/2 pH7 : at degree C
t1/2 pH9 : at degree C

Deg. Product	:	
Method	:	other
Year	:	1995
GLP	:	yes
Test substance	:	as prescribed by 1.1 - 1.4
Method	:	RCC states that it was responsible for performing the hydrolysis study according to the following EPA Guidelines and related amendments: (US) EPA 540/9-82-021: Pesticide Assessment Guidelines, Subdivision N: Chemistry: Environmental Fate, Section 161-1. (US) EPA: Pesticide Assessment Guidelines, Subdivision N, Environmental Fate, Section 161-1, Hydrolysis Studies, Standard Evaluation Procedure for Hydrolysis Studies, 1985. (US) EPA: Pesticide Assessment Guidelines, Subdivision N, Environmental Fate, Section 161-1, Hydrolysis Studies, Acceptance Criteria, 1989. (US) EPA: Pesticide Assessment Guidelines, Subdivision N, Environmental Fate, Section 161-1, Hydrolysis Studies, Addendum 3 on Data Reporting, 1988. (US) EPA: Pesticide Assessment Guidelines, Subdivision N, Environmental Fate, Section 161-1, Hydrolysis Studies, Guidance for Summarizing Hydrolysis Studies, 1989. (US)EPA: Pesticide Assessment Guidelines, Subdivision N, Environmental Fate, Section 161-1, Hydrolysis Studies, Study Compliance Checkllist for Hydrolysis Studies, 1989.
Result	:	The data demonstrated that during 30 days of incubation at 25 degrees C in aqueous solutions at pH 5, pH 7, and pH 9, the test substance was hydrolysed to an insignificant extent. Cumulative volatiles at the various sampling intervals specified under the test condition were all <0.05%. The mean percentages of radioactivity of the test substance recovered at the specified sampling intervals were 96.5% (standard deviation 2.6%) at pH 5, 95.1% (standard deviation 2.0%) at pH 7, and 93.8% (standard deviation 1.9%) at pH 9. Day 30 radioactivity of the parent compound (aqueous solution) were 98.6% for pH 5, 93.2% for pH 7, and 91.25 for pH 9.
Test condition	:	The test material was stored at about 4 degrees C in the dark. The C14 labeled material (Batch A 387) was radiolabeled at the carbonyl carbon. Radiochemical purity was >98% and remained at that purity for several months through the conductance of the study. The amount of C14 labeled material was 1 mg, corresponding to about 100.5 uCi. The labeled material was stored at ca -20 degrees in the dark. A number of reference compounds were collected for the study to assist in identification of decomposition products from hydrolysis. These were not actively used, since the extent of hydrolysis was negligible under the test conditions. Test solutions and test vessels were sterilized before incubation to minimize the process of microbial degradation during incubation. Bidistilled water was used and conductivity (2.3 uS/cm) and hardness (<>0.2 mmol/l) were determined. Since the hydrolysis rate was studied at three different pHs, buffered solutions were prepared and appropriately diluted. Sodium acetate and acetic acid were used to prepare the pH 5.0 buffered solution. TRIS and 0.1N HCl were used for the pH 7.0 buffered solution. Boric acid and 0.1N NaOH were used to prepare the pH 9.0 solution. No pH changes were observed due to the addition of the test article. Aliquots of the sterile buffer solutions containing the test article were incubated in Pyrex glass flasks in a water bath under darkness at the desired temperature of 25 degrees C (+-0.2 degrees C). The flasks were ventilated with moistened air through a sterile filter. The outcoming air was

passed through a CO2-trapping system (2NaOH) and through ethylene glycol for absorption of volatiles.

During the 30-day incubation period at every pH duplicate samples were taken at 9 time intervals (0, 3, 7, 10, 14, 17, 21, 24, and 30 days. After determination of total radioactivity, the duplicate samples of six time intervals (0, 3, 7, 14, 21, and 30 days) were further characterized for parent compound and degradation products.

Radioactivity was determined using a liquid scintillation counter equipped with DPM and luminescence options (TRI-CARB 2000 CA or 2500 TR). All measurements were performed for a counting time allowing a counting error below 5% or maximally 20 minutes. All values were corrected for instrumental background. Measurements were performed at least in duplicate.

Test substance : The test substance was N,N-dimethyldecanoic acid amide (CAS No. 14433-76-2), Batch No. 930129ELB02 of 98.8% purity.

Reliability : (1) valid without restriction
08.10.2002

(2)

Type :
t1/2 pH4 : at degree C
t1/2 pH7 : > 1 year at degree C
t1/2 pH9 : at degree C
Deg. Product : not measured
Method : other (calculated)
Year : 2002
GLP : no
Test substance : as prescribed by 1.1 - 1.4
Method : EPIWIN HYDROWIN identifies the amide group as the only group in the molecule for which a half life can be estimated. The remainder of the molecule is a saturated long-chain alkyl group that is not normally subject to hydrolysis.
Remark : The molecule is not expected to hydrolyze appreciably under neutral ambient conditions, because it does not contain functional groups expected to readily undergo hydrolysis.
Reliability : (2) valid with restrictions
21.09.2002

(7)

3.1.3 STABILITY IN SOIL

Type : laboratory
Radiolabel : yes
Concentration :
Soil temp. : degree C
Soil humidity :
Soil classif. :
Year :
Deg. Product :
Method : other
Year : 1995
GLP : yes
Test substance : as prescribed by 1.1 - 1.4
Method : The following guidelines were referenced for this study: (U.S.) EPA 540/9-82-021, Pesticide Assessment Guidelines, Subdivision N Chemistry: Environmental Fate, Section 163-1 Leaching and Adsorption/Desorption Studies, October 1982. The experimental design was partly based on the recommendations given by the OECD Guideline for Testing of Chemicals No. 106; "Adsorption/Desorption," adopted on May 12, 1981.
Result : The adsorption and desorption of the test substance was determined in

four soils: a sandy loam from Porterville, California, a loamy sand from Illinois, a silt loam from Illinois, and a loam from Iowa.

The adsorption of the test substance was determined after 6 hours. The adsorption Koc and desorption K'oc are given in the following table:

SOIL	Adsorption Koc	Desorption K'OC
Soil I	351	526
Soil II	630	934
Soil III	569	864
Soil IV	559	717

Source : The C. P. Hall Company
Test substance : The test substance was N,N-dimethyldecanoic acid amide (CAS No. 14433-76-2), Batch No. 930129ELB02, 98.8% purity. The 14C radiolabeled material was labeled at the carbonyl carbon and was of 99.4% radiochemical purity as determined by HPLC analysis.
Conclusion : The study author concluded that the test substance is of low or medium to low mobility in the soils tested.
Reliability : (1) valid without restriction
26.09.2002

(18)

3.2 MONITORING DATA

3.3.1 TRANSPORT BETWEEN ENVIRONMENTAL COMPARTMENTS

Type : fugacity model level III
Media : water - air
Air (level I) : 1.15
Water (level I) : 38.1
Soil (level I) :
Biota (level II / III) : .841
Soil (level II / III) : 59.9
Method : other
Year : 2002
Method : Inputs to run this program are:

CAS No. 14433-76-2
molecular weight = 199.34
Henry's Law Constant = 5.2e-007(Henrywin program)
vapor Pressure = 0.00157 mm Hg (Mpbpwin program)
liquid VP = 0.00355 mm Hg
M.P. = 60.8 degrees C (Mpbpwin program)
octanol-water partition coefficient = 2754.23
log Kow = 3.44 from KOWWIN program
soil Koc = 1.13e+003 (calc by EPIWIN KOC program)
air-water partition coefficient = 2.12665e-005
bioass to water partition coefficient = 551.646
temperature = 25 degrees C

Reliability : (2) valid with restrictions
20.09.2002

(6)

26.09.2002

3.3.2 DISTRIBUTION

3.4 MODE OF DEGRADATION IN ACTUAL USE

3.5 BIODEGRADATION

Type	:	aerobic
Inoculum	:	
Contact time	:	154 day
Degradation	:	= 50 % after 2.2 hour(s)
Result	:	other: rapidly biodegraded
Deg. Product	:	yes
Method	:	other
Year	:	1995
GLP	:	yes
Test substance	:	as prescribed by 1.1 - 1.4
Method	:	The following guidelines were followed: (U.S.) EPA 540/9-82-021: Pesticide Assessment Guidelines, Subdivision N: Chemistry: Environmental Fate, Section 162-1: Aerobic Soil Metabolism Studies, Section 162-2: Anaerobic Soil Metabolism Studies, October 18, 1982. (U.S.) EPA Pesticide Assessment Guidelines, Subdivision N, Environmental Fate, Section 162-1, Aerobic Soil Metabolism Studies. Standard Evaluation Procedure for Aerobic Soil Metabolism Studies, 1985. (U.S.) EPA Pesticide Assessment Guidelines, Subdivision N, Environmental Fate, Section 162-1, Aerobic Soil Metabolism Studies. Standard Evaluation Procedure for Aerobic Soil Metabolism Studies, 1985. (U.S.) EPA Pesticide Assessment Guidelines, Subdivision N, Environmental Fate, Section 162-1, Aerobic Soil Metabolism Studies. Addendum 5 on Data Reporting, 1987. (u.S.) EPA Pesticide Assessment Guidelines, Subdivision N, Environmental Fate, Section 162-1, Aerobic Soil Metabolism Studies, Acceptance Criteria, 1989.
Result	:	The mean recovery over the whold incubation period was 102.9% of the radioactivity applied. The test article was mineralized very fast and to a very high degree. After 1 day 33.5% of the radioactivity of the labeled test material was found as 14CO2, after 2 days this portion amounted to 63.5%. At the end of the incubation (154 days) 83.3% of the applied radioactivity was found as 14C02. Negligible amounts of volatiles other than 14CO2 were observed. Based on the data collected, a DT-50 value of 2.2 hours and a DT-90 value of 7.5 days were calculated. Metabolites like N,N-dimethylsuccinic acid monoamide and N,N-dimethylmalonic acid monoamide that were formed in the soil on day 1 were rapidly mineralized during further incubation.
Test condition	:	The aerobic degradation and metabolism of the test substance was investigated in one agricultural soil of the U.S. (sandy loam) at 20 +- degrees C and 75% of 1/3 bar moisture in the dark for 154 days. The labeled test material was applied at an initial concentration of 40.07 ug/100 g dry soil equivalent (8939485 dpm) corresponding to 400.7 ug/kg soil. The study was performed in duplicate in metabolism flasks. The sampling days were 0, 1, 2, 3, 4, 7, 14, 28, 77, and 154 days. The soil samples were extracted with acetonitrile and acetonitrile/water (1/1). The extracted radioactive residues were analyzed by TLC and confirmed

by HPLC. The amount of both parent substance and radioactive fractions was calculated.

Test substance : The test substance was N,N-dimethyldecanoic acid amide (CAS No. 14433-76-2), Batch No. 930129ELB02, 98.8% purity. The 14C radiolabeled material was labeled at the carbonyl carbon and was of >98% radiochemical purity as determined by TLC and HPLC analysis.

Reliability : (1) valid without restriction

11.11.2002 (19)

Type : aerobic
Inoculum :
Contact time : 50 day
Degradation : = 50 % after .3 day
Result :
Deg. Product : yes
Method : other
Year : 1995
GLP : yes
Test substance : as prescribed by 1.1 - 1.4
Method : The following guideline was followed:

Richtlinie Teil IV, 4-1 BBA der Bundesrepublik Deutschland: Verbleib von Pflanzenschutzmitteln im Boden - Abbau, Umwandlung and Metabolismus, Dezember, 1986.

Result : Based on data collected during a 50 day incubation period DT-50 values of 0.02 day (Soil A) to 0.27 days (Soil C) were calculated. The DT-90 values amounted to 0.65, 1.14 and 2.46 days for soils A, B and C respectively. The test substance was mineralized to a very high degree. Totally >= 83% of the applied radioactivity were found in the form of 14CO2 at the end of the 50 day incubation period. Two metabolites were found - N,N-dimethylsuccinic acid monoamide and N,N-dimethylmalonic acid monoamide. These metabolites rapidly degraded further to eventually form 14CO2.

Test condition : The rate of decline (DT-50 and DT-90 values) of the test substance was determined in three soil incubated in the dark for 50 days at 20 degrees C under aerobic conditions. The three soils were [A (silt loam), B (loamy sand) and C (silt loam) were treated with the radiolabeled test substance at a rate of 81 ug/100g of soil.

The soil samples were extracted with acetonitrile, acetonitrile/water (1/1) and water.

The extracted radioactive residues were analyzed by TLC and confirmed by HPLC. The amount of both parent substance and radioactive fractions was calcula

Test substance : The test substance was N,N-dimethyldecanoic acid amide (CAS No. 14433-76-2), Batch No. 930129ELB02, 98.8% purity. The 14C radiolabeled material was labeled at the carbonyl carbon and was of 100% radiochemical purity.

Conclusion : The study author concluded that the rate of mineralization under the test condition was very high in all three soil types studied, and amounted to > 70% of the applied radioactivity after 4 days.

08.10.2002 (14)

Type	:	aerobic
Inoculum	:	
Deg. Product	:	
Method	:	other: calculated
Year	:	2002
GLP	:	no
Test substance	:	as prescribed by 1.1 - 1.4
Remark	:	The EPIWIN/BIOWIN program estimates biodegradabilty of the test substance using a mathematical algorithm that sums up individual chemical bond fragment valuations for biodegradation. The result is consistent with general knowledge that intermediate length aliphatic hydrocarbon chains having a terminal amide function are generally recognized to biodegrade readily.
Result	:	EPIWIN/BIOWIN predicts that the test substance will biodegrade fast.
Reliability	:	(2) valid with restrictions A reliability rating of 2 was assigned, because the determination was estimated by a model.

11.11.2002 (13)

3.6 BOD5, COD OR BOD5/COD RATIO

3.7 BIOACCUMULATION

3.8 ADDITIONAL REMARKS

4.1 ACUTE/PROLONGED TOXICITY TO FISH

4.2 ACUTE TOXICITY TO AQUATIC INVERTEBRATES

4.3 TOXICITY TO AQUATIC PLANTS E.G. ALGAE

4.4 TOXICITY TO MICROORGANISMS E.G. BACTERIA

4.5.1 CHRONIC TOXICITY TO FISH

4.5.2 CHRONIC TOXICITY TO AQUATIC INVERTEBRATES

4.6.1 TOXICITY TO SOIL DWELLING ORGANISMS

4.6.2 TOXICITY TO TERRESTRIAL PLANTS

4.6.3 TOXICITY TO OTHER NON-MAMM. TERRESTRIAL SPECIES

4.7 BIOLOGICAL EFFECTS MONITORING

4.8 BIOTRANSFORMATION AND KINETICS

4.9 ADDITIONAL REMARKS

(1) Bayer AG, Leverkusen Germany, Laboratory Project ID 14 180 0855, J. Krohn, Density of Dimethyldecanamide, January 6, 1995.

(2) Burri, R. 1995. Hydrolysis determination of (1-14C) N,N-dimethyldecanoic acid amide at pH 5, 7, and 9, R C C Umweltchemie AG (P. O. Box CH-4452 Itingen/BL, Switzerland) Study No. RCC Project 340290, May 23, 1995.

(3) Burri, R. 1995. Photodegradation study of (1-14C) N,N-dimethyldecanoic acid amide in water at pH 5, R C C Umweltchemie AG P.O. Box CH-4452 Itingen/BL, Switzerland, Study Project Number RCC Project 340312, June 15, 1995.

(4) Burri, R. 1996. Photodegradation study of (1-14C) N,N-dimethyldecanoic acid amide on soil, R C C Umweltchemie AG P.O. Box CH-4452 Itingen/BL, Switzerland, Study Project Number RCC Project 370247, January 4, 1996.

(5) EPIWIN AOP Program (v1.90).

(6) EPIWIN Fugacity Level III Program.

(7) EPIWIN HYDROWIN Program (v1.67).

(8) EPIWIN KOWWIN Program (v1.66).

(9) EPIWIN MPBPWIN Program (v1.40)

(10) EPIWIN MPBPWIN Program (v1.40).

(11) EPIWIN MPBPWIN program (v1.40).

(12) EPIWIN WSKOW Program (v1.40).

(13) EPIWIN/BIOWIN (v4.00)program.

(14) Flueckiger, J. 1995. [1-14C]N,N-Dimethyldecanoic acid amide: Degradation in three soils incubated under aerobic conditions, RCC Umweltchemie AG, Study Project No. RCC Project 340345, October 30, 1995

(15) Krohn, J. 1993. Partition coefficient of dimethyloctanamide and dimethyldecanamide, Beyer AG, Leverkusen Germany, Laboratory Project ID 14 700 0780, December 3, 1993.

(16) Krohn, J. 1994. Vapour pressure curve of dimethyldecanamide, Bayer AG, Leverkusen, Germany, Laboratory Project ID 12 200 0782, June 30, 1994.

(17) Krohn, J. 1994. Water solubility of dimethyloctanamide and dimethyldecanamide Bayer AG, Leverkusen, Germany, Laboratory Project ID 14 410 0779, June 9, 1994.

(18) RCC Umweltchemie AG, Study Project No. RCC Project 340356, U. Morgenroth, Adsorption/Desorption of N,N-Dimethyldecanoic acid amide on four soils, December 20, 1995.

(19) Wyss-Benz, M. and A. Tschech. 1995. [1-14C]N,N-Dimethyldecanoic acid amide: Degradation and metabolism in one U.S. soil, incubated under aerobic conditions, RCC Umweltchemie AG, Study Project No. RCC Project 340334, September 7, 1995.

7.1 END POINT SUMMARY

7.2 HAZARD SUMMARY

7.3 RISK ASSESSMENT